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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

Roy A. Ostgaard, et al.

Serial No.: 09/156,952

Filed: September 18, 1998

For: SAMPLE VIAL FOR USE IN PREPARING CYTOLOGICAL SPECIMEN

Confirmation: 1770

Group Art Unit: 1743

Examiner: Dwayne K. Handy

APPEAL BRIEF TRANSMITTAL

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Transmitted herewith is an Appeal Brief (13 pages) in triplicate, for the above-identified application.

The items checked below are appropriate.

☒ Appeal Brief Fee:

- ☒ Large Entity Fee of $500.00; or
- ☐ Small Entity Fee of $250.00.
- ☐ Applicant(s) claim Small Entity Status under 37 CFR § 1.27.

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Respectfully submitted,

Dated: September 9, 2005

By: _____
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APPEAL BRIEF-CFR 41.37

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Brief is in furtherance of the Notice of Appeal, filed in this case on July 11, 2005, and contains the following items in the order indicated below as required by CFR 41.37:

I. Real Party in Interest
II. Related Appeals and Interferences
III. Status of Claims
IV. Status of Amendments
V. Summary of Claimed Subject Matter
VI. Grounds of Rejection to be Reviewed on Appeal
VII. Arguments
VIII. Appendix of Claims Involved in the Appeal

I. Real Party in Interest

The real party in interest in this appeal is Cytyc Corporation of Boxborough, Massachusetts, a corporation organized and existing under laws of the Commonwealth of Massachusetts.

II. Related Appeals and Interferences

There are no appeals or interferences that will directly affect, or be directly affected by, or have a bearing on the Board's decision in this appeal.

III. Status of Claims

This application includes claims 1-26. Of these claims, claims 1-8, 10, and 12-27 are pending, and the remaining claims 9 and 11 have been cancelled. Of the pending claims, claims 1-8, 10, and 12-27 stand rejected, leaving no claims allowed. The claims on appeal are claims 1-8, 10, and 12-27.

IV. Status of Amendments

All amendments have been entered.

V. Summary of Invention

Although the invention should not be limited to the preferred embodiments described in the specification, the invention will now be described in terms of one preferred embodiment in order to aid in understanding the invention.

The invention, as defined in the claims on appeal, is directed to a sample vial 10 for use in an automated test apparatus. The sample vial 10 generally includes a body 12, a cap 14 releasably engagable with the body 12, and a seal 24 disposed between the body 12 and cap 14.

(see page 8, lines 14-20 and page 9, lines 22-24; Figs. 1 and 5). The cap 14 comprises a torque pattern 38 formed by a plurality of radially disposed ribs 16, thereby allowing the cap 14 to be installed on or released from the body 12 using a rotatable interface that engages the radially disposed ribs 16. (see page 9, lines 8-14; Fig. 6). The body 12 comprises anti-rotation lugs 18 that react against proximate structure of an automated test apparatus when the body 12 is installed in the proximate structure to facilitate automated removal and installation of the cap 14 on the body 12 (see page 8, line 21 to page 9, line 4; Fig. 1). Specifically, the anti-rotation lugs 18 have a geometry that provides control over the rotation and penetration depth (i.e., translation) of the body 12 relative to the bore 52 of an interface 54 (illustrated in Fig. 7A) and the bore 62 of a vial sleeve 64 (illustrated in Fig. 7B)(see page 13, line 12 to page 14, line 2).

For example, after the vial 10 has been filled with a sample, the body 12 can be disposed within the bore 52 the interface 54, with the anti-rotation lugs 18 abutting against the vertical faces 58 of ramps 56 when clockwise rotation of the body 12 is attempted during installation of the cap 14. (see page 13, lines 12-21). In addition, the body 12 can be disposed within the bore 62 of a vial sleeve 64 illustrated in Fig. 7B, with the anti-rotation lugs 18 being received in the slots 66. (see page 13, line 22 to page 14, line 2). Thus, counter-clockwise rotation of the body 12 is prevented when the cap 12 is removed in order to dispense the sample, and clockwise rotation of the body 12 is prevented when the cap 12 is reinstalled on the body after the sample has been dispensed. (see page 14, lines 9-11).

Each of the anti-rotation lugs 18 has a lower-most surface that extends radially outwardly from the outer surface of the body 12. (see Fig. 5). This lower-most surface has features that facilitate proper interaction with the ramps 56 of the unidirectional interface 54 and the slots 66 of the vial sleeve 64. First, the lower-most surface is flat to maximize the area that

comes in contact with the vertical face 58 of the respective ramp 56. (see Figs. 5 and 7A). Second, the lower-most surface is substantially perpendicular to the outer surface of the body 12, so that the anti-rotation lugs 18 properly engage the bottom surfaces of the ramps 56 and slots 66. (see Figs. 5 and 7A). Third, the lower-most surface is closer to the open end of the body 12 than to the closed end, allowing the body 12 to be properly inserted within the bore 52 of the interface 54 and the bore 62 of the vial sleeve 64. (see Figs. 5, 7A, and 7B).

VI. Grounds of Rejection to be Reviewed on Appeal

Whether claims 1-8, 10, and 12-26 are unpatentable under 35 U.S.C. §103 as being obvious over U.S. Patent No. 5,894,733 ("Brodner") in view of U.S. Patent No. 5,855,289 ("Moore").

VII. Arguments

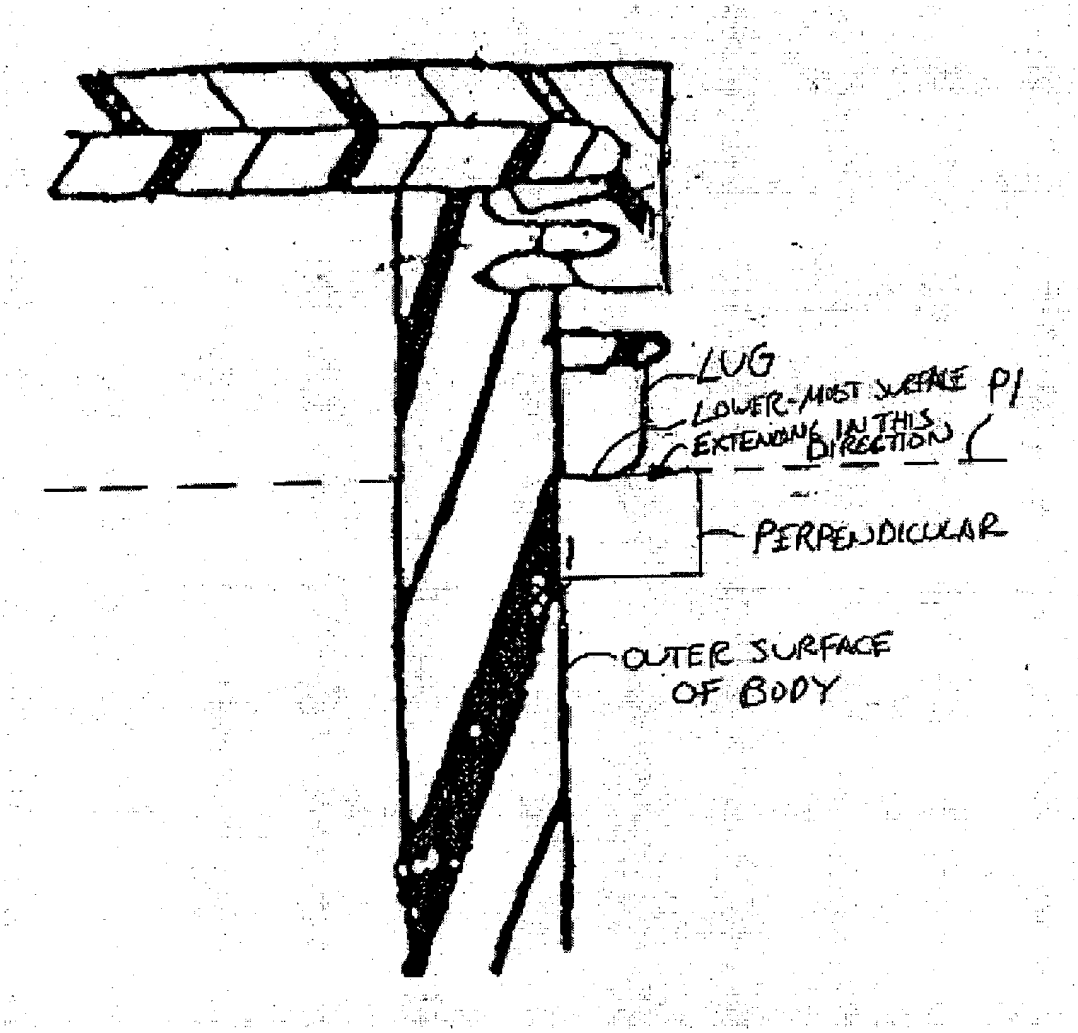
Applicant respectfully submits that the Examiner erred in rejecting claims 1-8, 10, and 12-27 under 35 U.S.C. §103 as being obvious over Brodner in view of Moore. The Examiner indicated that Brodner discloses all of the elements recited by claim 1, with the exception of a torque pattern with a plurality of radially disposed ribs (See Office Action, dated July 14, 2004, and then used Moore to provide this missing element. Applicant submits, however, that the teachings of Brodner and Moore, even if properly combined, would not result in the claimed invention.

To establish obviousness, it must be found that the differences between the claimed invention and the prior art would have been obvious to a person having ordinary skill in the art. Graham v. John Deere Co., 383 U.S. 1, 17 (1966). Applicants believe that the differences

between the claim 1 invention and the teachings of Brodner and Moore would not have been obvious to a person having ordinary skill in the art.

In particular, even assuming that Brodner and Moore can be combined, there is a significant element not disclosed in the resulting vial—i.e., a lug having a generally flat, lower-most surface that extends radially outwardly from the outer body surface of the vial along a plane perpendicular to the body outer surface. Notably, the issue before this Board is not whether it would be obvious to modify the lugs of the Brodner device to include this feature (an issue that was before this Board in the previous appeal), but rather whether the lugs of the Brodner device include this feature at all.

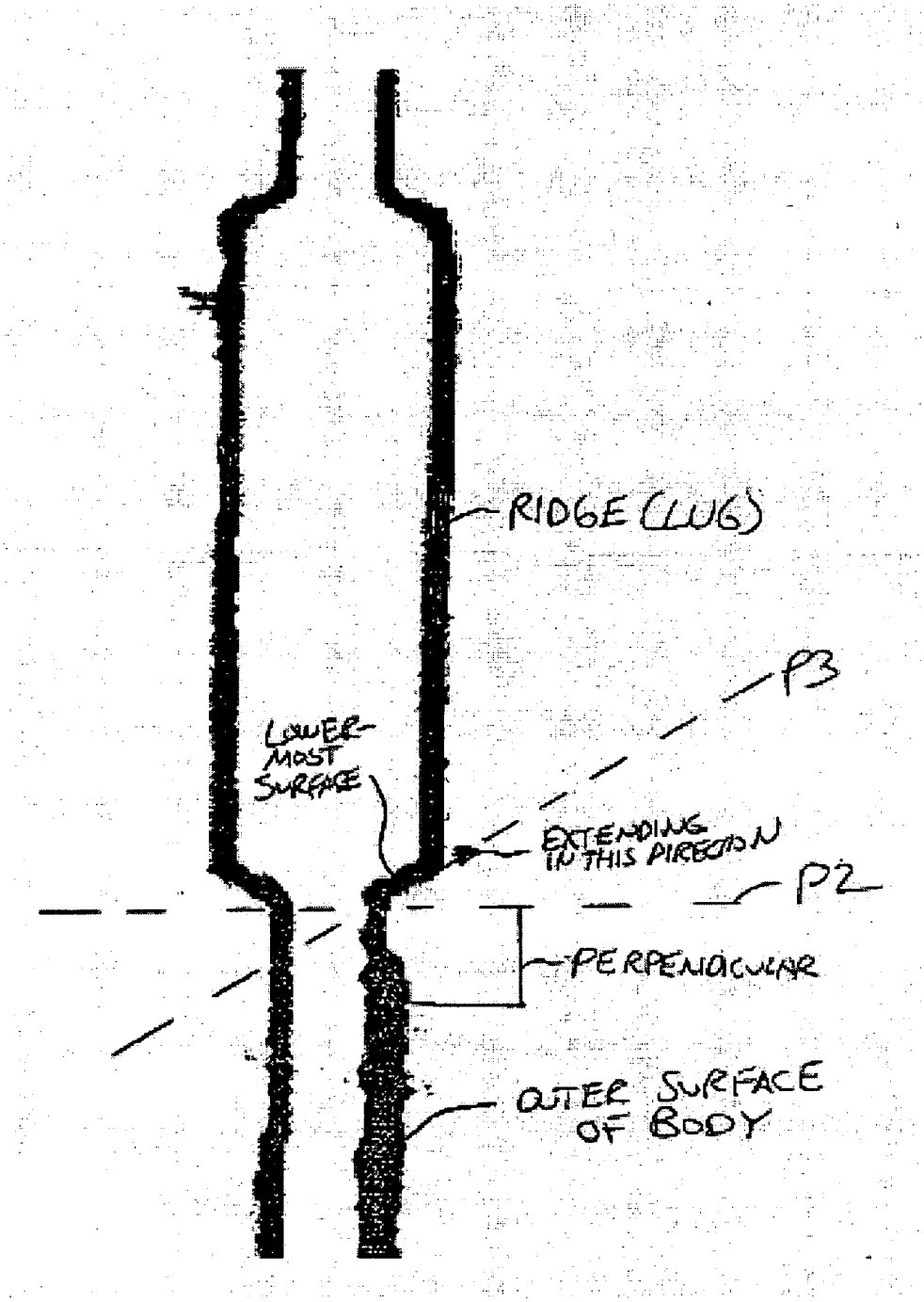
Fig. 5 of the present application is reproduced below to illustrate this claimed feature. As can be seen, a lower-most surface of the lug 18, which is generally flat, extends radially outward from the outer surface of the body 12 of the vial along a plane P1 (along the direction of the arrow) that is perpendicular to the body outer surface.



Brodner, which the Examiner has referred to as disclosing this feature, is directed to a specimen vial 10 and labeled sleeve 12 that, in combination, purport to overcome difficulties apparently associated with labeling containers stored at cryogenic temperatures. (col. 1, lines 7-12, 23-26; Fig. 2). The vial 10 is cylindrically shaped and includes vertically spaced ridges 34 disposed about its exterior surface 30. (col. 2, lines 61-63; Figs. 1, 2, and 4.) (Brodner Figure 2 (left-hand drawing) seemingly misidentifies the ridges 34 by using reference designator 10). The sleeve 12 also includes vertically spaced ridges 58 disposed about its interior surface 52. (col. 3, lines 30-32, Fig. 2). The vial 10 is inserted into sleeve 12, resulting in a "nested engagement," wherein the sleeve ridges 58 are in "pressing engagement" with the vial ridges 34. (col. 3, lines

42-47). The sleeve 12 operates similarly in relation to the tray 16. Specifically, the sleeve 12 includes vertically spaced ridges 56 disposed about its exterior surface 44. (col. 3, lines 28-30). The aperture opening 66 of the tray 16 includes vertically spaced ridges 68 that are in "pressing engagement" with the ridges 56 of the exterior surface 44 of the sleeve 12 when the sleeve 12, with the vial 10 nested therein, is placed in the aperture 62 of the tray. (col. 3, lines 34-41).

Fig. 2 of Brodner, reproduced below, illustrates the ridges 56 of the vial sleeve 12. Even assuming that the ridges 56 can be considered lugs that radially extend outward from the outer surface of a vial, the lower-most surface of each ridge 56 does not extend along a plane P2 that is perpendicular to the outer surface of the so-called vial. Rather, as clearly illustrated in Fig. 2, the lower-most surface of each ridge 56 extends along a plane P3 (in the direction of the arrow) that is angled to the outer surface of the vial.



Despite this clear distinction between the claims and Brodner, the Examiner has maintained that the lower-most surfaces of the Brodner ridges 56 do extend along a plane that is perpendicular to the outer surface of the vial. In particular, the teachings of Brodner were originally characterized by the Examiner as follows:

> Brodner teaches the use of polyprophylene (column 3, lines 11-13) combination 14 sample vial comprising a sleeve 12 and inner container 10. The combination having an outer surface 55, an open end and closed bottom end (Fig. 2). The vial combination comprising a plurality of integral anti-rotation lugs 56 about the outer surface of the cylindrical body (Figs. 2-3). Wherein the anti-rotation lug comprises a flat, longitudinally disposed surface extending radially outwardly from the body outer surface, which is substantially perpendicular to the body of the vial. (page 3 of Office Action, dated July 14, 2004)(emphasis added).

To further clarify the claimed invention, Appellant subsequently amended the claims to require the anti-rotation lug to radially extend outwardly from the body outer surface along a plane perpendicular to the body outer surface. (See Amendment and Response, dated October 13, 2004). Appellant then pointed out that the lower-most surfaces of the ridges 56 are tapered or beveled, and therefore extend radially outward along a plane that appeared to be about 45 degrees to the outer surface of the sleeve structure 12—not a plane that was perpendicular to the outer surface of the sleeve structure 12. (See page 5 of Amendment and Response, dated October 13, 2004).

The Examiner responded by stating that the point at which the ridge 56 extends from the outer surface would qualify as the lower-most surface of the ridge 56 in that the lower-most surface still extends away from the outer surface of the body. (See pages 3-4 of Office Action, dated January 11, 2005). At the request of Appellant to clarify this statement, the Examiner transmitted a marked-up copy of Fig. 2 of Brodner (attached hereto), illustrating how the lower-most surface of the ridge 56 extends along the y-axis out of the page. Without amending the claims, Appellant subsequently argued that the lower-most surface does not extend along in the y-direction out of the page, but rather extends off-axis from the y-axis due to its tapered nature. (See pages 1-2 of Response after Final, dated March 11, 2005).

The Examiner responded, stating:

> Applicant appears to be arguing that the line formed by the tapered edge is not perpendicular to the body surface. The Examiner, however, refers applicant to the claim. The claim recites a lug "comprising a generally flat lower-most surface along a plane perpendicular to said outer body surface." That is, the limitation appears to define the plane in which the lug exists – not the angle that a line formed by the taper (or the taper itself) with the body surface.
>
> The lug forms an element that is in a defined plane once it begins to extend from the body surface. As noted by applicant, the Examiner has referred to this as the y-direction in the diagram. This plane – no matter how much the lug element tapers – is still defined two-dimensionally in this single plane. For example, if one were to draw a line that started at the beginning of the taper and followed the taper (start from the body surface, extending out of the page) to infinity the line would still lie in the same plane of element 62. That plane is the plane extending out of the page. This defined plane is perpendicular to the surface of the body outer surface. This is what the claim requires. (See Advisory Action, dated June 29, 2005).

Admittedly, Appellant unclear as to what the Examiner is referring to. The claim simply requires the lower-most surface of the lug to extend "radially outwardly from said body outer surface along a plane perpendicular to said body outer surface." The Examiner states that this limitation appears to define the plane in which the lug exists. It does not. It defines the plane in which the lower-most surface of the lug exists. That is, the lower-most surface of the lug extends in the plane, as illustrated in Fig. 5 above. The lower-most surface of the Brodner ridge 56 extends in a plane, but this plane is not perpendicular to the outer surface of the body, as illustrated in Fig. 2 above. The Examiner states that if one were to draw a line that started at the beginning of the taper and followed the taper to infinity, the line would still lie in the same plane as the ridge 56. Appellant fails to understand what it means to lie in the same plane as the ridge 56, but clearly, this line does not lie in a plane that is perpendicular to the outer surface of the body, as required by the claims.

Thus, Brodner does not disclose a lug that has a lower-most surface that radially extends outwardly from an outer surface of a vial along a plane that is perpendicular to the outer body

surface, and thus, the differences between the sample vial of claims 1-8, 10, and 12-26 and the teachings of Brodner and Moore would not have been obvious to a person having ordinary skill in the art. As such, Applicants respectfully submit that claims 1-8, 10, and 12-26 are patentable over the prior art of record.

VIII. Appendix of Claims Involved in the Appeal

1. A sample vial for use in an automated test apparatus, the sample vial comprising:

a body comprising an outer surface, an open end, a closed end, and at lease one anti-rotation lug about said body outer surface, the anti-rotation lug comprising a generally flat, lower-most surface extending radially outwardly from said body outer surface along a plane perpendicular to said body outer surface, the lowermost surface located closer to the open end than to the closed end;

a cap releasably engagable with said body, said cap comprising an outer surface and a torque pattern on said cap outer surface, said torque pattern comprising a plurality of radially disposed ribs; and

a seal disposed between said body and said cap so as to be capable of forming a substantially fluid-tight seal therebetween,

wherein the lower-most surface is accessible when the cap is engaged with the body for reacting against proximate structure of the automated test apparatus when installed therein to facilitate at least one of automated removal and installation of the cap.

2. The sample vial of claim 1 wherein said body comprises a translucent material.

3. The sample vial of claim 1 wherein said body comprises polypropylene.

4. The sample vial of claim 1 wherein said cap further comprises knurling along an

outer perimeter thereof.

5. The sample vial of claim 1 wherein said cap comprises polypropylene.

6. The sample vial of claim 1 wherein said seal comprises a multicomposite material.

7. The sample vial of claim 1 wherein a substantially fluid-tight seal between said body and said cap is formed when between about 5 and 50 inch-pounds of torque is applied.

8. The sample vial of claim 7 wherein a substantially fluid-tight seal between said body and said cap is formed when about 20 inch-pounds of torque is applied.

10. The sample vial of claim 1 wherein said torque pattern comprises six radially disposed equi-spaced ribs.

12. The sample vial of claim 1 wherein said body comprises a plurality of circumferentially-disposed lugs.

13. The sample vial of claim 12 wherein said body comprises six equi-spaced circumferentially-disposed lugs.

14. The sample vial of claim 12 wherein said plurality of circumferentially-disposed lugs are disposed proximate said open end.

15. The sample vial of claim 1 wherein said body further comprises fluid level indicia disposed on said outer surface thereof.

16. The sample vial of claim 15 wherein said fluid level indicia comprises a frosted annular band disposed circumferentially about said body outer surface.

17. The sample vial of claim 15 wherein said fluid level indicia comprises at least one fill line.

18. The sample vial of claim 17 wherein said fluid level indicia comprises an upper

fill line and a lower fill line.

19. The sample vial of claim 1 wherein said cap comprises a first alignment marker said body comprises a second alignment marker, wherein said first and second alignment markers indicate a fluid-tight seal when at least aligned.

20. The sample vial of claim 19 wherein said cap may be removed from said body by the application of less than about 25 inch-pounds of torque, when said first marker is at least aligned with said second marker.

21. The sample vial of claim 1 wherein said seal is disposed within said cap.

22. The sample vial of claim 1 wherein said cap further comprises a first screw thread, said body further comprises a second mating screw thread, said cap and said body being releasably engagable by means of said first screw thread and said second screw thread.

23. The sample vial of claim 1 wherein said body further comprises sample indicia.

24. The sample vial of claim 23 wherein said sample indicia comprises a bar code.

25. The sample vial of claim 1 wherein said body further comprises a flange proximate said open end.

26. The sample vial of claim 1 wherein the proximate structure is selected from the group consisting of a storage tray and a vial sleeve.

27. The sample vial of claim 1 wherein the body is designed to be inseparable.

Respectfully submitted,

Dated: September 9, 2005 By: _____

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